REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. By the present amendment, claims 21-23, 32, 37, 80 and 96 are cancelled. Claims 1 is amended, and new claims 151-159 are added, to more specifically focus on certain aspects of the present invention. Support for these claims is provided in the application as filed, and this amendment does not introduce new matter. In addition, it should be noted that the amendment is made without acquiescence to any of the rejections and without prejudice to the prosecution of claims directed to any subject matter modified or removed by the amendments in one or more related continuing applications.

Telephonic Interview

Applicants wish to thank the Examiner for her willingness to conduct a telephonic interview with Applicants' representative on July 20, 2010, during which the various bases of rejection and claim features were discussed.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 20-23, 32, 37, 80, and 96 stand rejected under 35 U.S.C. § 112, for allegedly failing to comply with the written description requirement. Applicants traverse this basis of rejection and submit that the instant claims satisfy the written description requirement. Nonetheless, without acquiescence to this basis of rejection, the instant claims have been amended to more specifically describe various steps of the claimed method. In particular, independent claims 1 and 151 explicitly recite the steps of "processing adipose tissue obtained from a patient to release cells therein" and "separating the released cells from lipids." Support for this amendment is provided throughout the instant specification, including, *e.g.*, at page 4, lines 1-4, page 8, lines 17-18, page 10, lines 3-4, and page 13, lines 12-16. In addition, these claims also recite various techniques for performing these steps.

Applicants submit that, as disclosed in the specification and recited in the present claims, the instant application reasonably conveys to a person skilled in the art that Applicants possessed the claimed embodiments at the time the application was filed. Applicants submit that satisfaction of the written description requirement requires merely that the specification contain a written description of the invention, for the primary purposes of demonstrating that the applicants invented the claimed subject matter and placing the public in possession of the invention. *See, e.g., In re Barker*, 559 F.2d 588, 592 n.4 (CCPA 1977) and *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). Written description is adequate when the specification describes the claimed embodiments in sufficient detail to convey to a person skilled in the art that the Applicant was in possession of the claimed embodiments at the time of filing, even if each and every species encompassed by the claims is not explicitly described in the specification. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). The Federal Circuit Court of Appeals has articulated that with respect to the biological art, "[p]recedent illustrates that the determination of what is needed in a specification to support generic claims related to biological subject matter depends on a variety of factors, including existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter" (*Capon v. Eshhar,* 418 F.3d 1349, 1359 (Fed. Cir. 2005), citing *In re Wallach*, 378 F.3d 1330, 1333-34 (2004); *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004); *Singh v. Brake*, 317 F.3d 1334, 1343 (Fed. Cir. 2003)); (*see also* M.P.E.P. § 2163.02)). Furthermore, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (*In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976)).

Applicants submit that the instant specification adequately describes the various steps of the claimed embodiments of a method for preparing a cell population comprising stem cells for introducing into a patient. Clearly, in view of the detailed description of various techniques that may be used to perform the recited steps, a person skilled in the art would

appreciate that the Applicants were in possession of the claimed embodiments at the time of filing. Thus, the instant specification provides written description of the claimed embodiments.

Each of the specific bases for this rejection set forth by the Examiner are addressed in turn below.

(1) Claims 1 and 21 stand rejected on the basis that they recite the step of processing adipose tissue "to separate the cells therein from lipids," which the Examiner states is not adequately described in the specification. The Examiner essentially asserts that adipose tissue does not contain free-floating extracellular lipids, so lipids can only be separated from adipose cells by destroying the cells, and that the instant specification fails to provide guidance or specific examples for carrying out this step of the claimed method.

As an initial matter, Applicants note that claim 21 is cancelled by the present amendment, thus obviating this basis of rejection with respect to claim 21. With respect to the remaining claims, Applicants submit that the instant specification provides sufficient guidance regarding how to separate cells released from adipose tissue from lipids, to satisfy the written description requirement. For instance, Example 1, which describes an exemplary method of the present invention, specifically describes how lipids are separated from cells. According to this method, at steps (t) and (u), following enzymatic digestion, cells are pelleted by centrifugation, and the supernatant, which contains lipids (*i.e.*, fat layer), is poured off, thus separating the cells from the lipids. One of skill in the art would also understand that during the processing of adipose tissue to release cells therein, which may comprise physical cutting and/or enzymatic digestion, certain cells will, in fact, be destroyed. Typically, these include the more fragile, mature adipocytes, resulting in the release of intracellular lipid, which will collect in a fat layer that floats above the aqueous solution comprising the cells. Accordingly, in view of the instant specification and general knowledge in the art, the skilled artisan would both appreciate that free lipid would be released during the processing of adipose tissue and understand how to separate cells from such lipid. Thus, the instant specification clearly provides adequate written description of this step of the claimed method.

(2) Claim 32, 37 and 96 stand rejected on the basis that they recite that the starting material is a collagen-based tissue, which may be "umbilical cord matrix," but according to the

Examine, umbilical cord matrix tissue does not contain lipid, so it is not clear how cells from this tissue may be separated from lipids.

Without acquiescence to this basis of rejection, claims 32, 37 and 96 have been canceled, thereby obviating this basis for rejection.

(3) In addition, the Examiner asserts that certain claims recite that the stem cells are not isolated from other purified cells, yet the specification describes a method wherein blood is washed from the tissue, and since blood is a cell type, the exemplified method appears to separate stem cells at least from blood cells. Accordingly, the Examiner states the instant specification does not clearly describe the claimed method.

Without acquiescence to this basis of rejection, the claims have been amended to clarify that stem cells are not isolated from other cell types after separation of the released cells from lipid or non-cellular tissue components. Accordingly, while some blood cells may be lost during rinsing of the adipose tissue sample before the samples are completely processed to release cells therein, once cells are released and separated from lipid or non-cellular tissue components, no steps are taken to isolate stem cells from other types of cells. This is clearly demonstrated in Example 1, which describes that minced tissue is rinsed (step (o)) before collagenase treatment (step (p)) and before cells are isolated from lipid (step (u)). Thus, Applicants submit that the instant specification provides adequate written description of the claimed method.

In response to the Examiner's comment that the previously submitted Catania Declaration describes a method that includes a step where cells are lysed, Applicants would like to clarify that the Catania Declaration describes experiments that compare cell populations produced according to the claimed method to cell populations produced by a method that includes the step of lysing red blood cells. It is only the comparator method that includes the step of lysing red blood cells.

(4) The Examiner further indicates that the specification does not make clear whether "fat particles" removed according to step (i) of the method exemplified in Example 1 are "pieces of adipose tissue" or "globules of lipid."

Applicants respectfully traverse this basis of rejection and submit that based upon the description provided by the instant specification, the skilled artisan would clearly understand the "fat particles" to be pieces of fat tissue resulting from mincing of the fat tissue. As described in Example 1, the fat (adipose tissue) sample is minced in a petri dish, which is then rinsed with PBS to collect all of the minced fat particles into a tube for subsequent enzymatic digestion. Thus, the instant specification provides clear written description support for this aspect of the claimed method.

Accordingly, the instant specification describes the claimed methods with sufficient, relevant, identifying characteristics to convey to a person skilled in the art that Applicants possessed the claimed embodiments at the time the application was filed. Applicants, therefore, submit that the instant claims satisfy the written description requirement under 35 U.S.C. § 112, first paragraph, and respectfully requests withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-3, 20-23, 32, 37, 80, and 96 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants traverse this basis of rejection and submit that the instant claims are clearly definite. Each of the various bases for this rejection are addressed in turn below.

(1) The Examiner asserts that claims 1 and 21 (and claims 2, 3, 20, 22 and 23 dependent therefrom) recite a method that includes separating lipid from adipose tissue-derived cells, which would require lysing and destroying the cells. Thus, the Examiner finds it unclear how lipid can be separated from cells found in adipose tissue without removing the stem cells.

Applicants traverse this basis of rejection and submit that the instant claims are clear and definite. As discussed above in the context of the related written description rejection, the skilled artisan would understand that processing of the adipose tissue leads to lysis of certain fragile cells, including mature adipocytes, resulting in the release of lipid, and that the isolated cells are separated from this lipid.

(2) The Examiner asserts that claims 32, 80 and 96 require beginning with a "collagen-based-tissue" and then separating the cells therein from lipids. The Examiner states

this is confusing since there is no requirement that the collagen-based tissue contain lipids, and the scope of the processing step in each claim cannot be determined.

Without acquiescence to this basis of rejection, claims 32, 80 and 96 have been cancelled, thus obviating this basis of rejection.

(3) Furthermore, the Examiner asserts that it is unclear whether the "device comprising an array of screens" in claim 80 separates the cells from the lipid or serves another purpose.

Without acquiescence to this basis of rejection, claim 80 has been cancelled, this obviating this basis of rejection.

(4) Applicants also note that new claim 151 describes a method that includes a step (b) comprising "separating the released cells from non-cellular tissue components." Applicants submit that the term "non-cellular tissue components" would be readily understood by one of skill in the art, such that this phrase is clear and definite. In particular, one of skill in the art would be well-apprised as to the components of adipose tissue, and would understood that they include both cells and non-cellular materials. Furthermore, components of adipose tissue have been described in the art. For example, one reference describes that "in adult mammals, the major bulk of adipose tissue is a loose association of lipid-filled cells called adipocytes, which are held in a framework of collagen fibers. In addition to adipocytes, adipose tissue contains stromal-vascular cells including fibroblastic connective tissue cells, leukocytes, macrophages, and pre-adipocytes (not yet filled with lipid), which contribute to structural integrity" (Albright, A.L. and Stern, J.S. (1998). Adipose tissue. In: Encyclopedia of Sports Medicine and Science, T.D. Fahey (Editor). Internet Society for Sport Science: http://sportsci.org. 30 May 1998). Accordingly, based upon knowledge in the art and the description provided in the instant application, one of skill in the art would clearly understand the meaning of "non-cellular tissue components" with respect to adipose tissue, and this term is, therefore, clear and definite.

In view of the above comments, Applicants submit that the instant claims are clearly definite in view of the instant specification and respectfully request reconsideration and withdrawal of the rejections under Section 112, second paragraph.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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